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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/635,027	08/04/2000	Ranjit Banerjee		2670

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Arthur I Degenholtz
32 Vandelinda Ave
Teaneck, NJ 07666

EXAMINER

WHISENANT, ETHAN C

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 12/20/2001

6

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary

Application No.

09/635,027

Applicant(s)

R. BANERJEE

Examiner

Ethan C. Whisenant

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. The applicant's Response to the Office Action has been entered. The applicant's response was received on 18 OCT 01 and has been entered as paper no. 5. The claim(s) pending in this application is/are **Claim(s) 1**. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

2. The amendment to the claims filed on 23 OCT 01 does not comply with the requirements of 37 CFR1.121(c). Amendment to the claims filed after 01 MAR 01 must comply with 37 CFR1.121© which states:

© Claims

(1) Amendment by rewriting, directions to cancel or add : Amendments to a claim must be made by rewriting such claim with all changes (e.g., additions, deletions, modifications) included. The rewriting of a claim (with the same number) will be construed as directing the cancellation of the previous version of that claim. A claim may also be canceled by an instruction.

(I) A rewritten or newly added claim must be in clean form, that is, **without markings to indicate the changes that have been made**. A parenthetical expression should follow the claim number indicating the status of the claim as amended or newly added (e.g., "amended," "twice amended," or "new").

(ii) If a claim is amended by rewriting such claim with the same number, the amendment must be accompanied by another version of the rewritten claim, on one or more pages separate from the amendment, marked up to show all the changes relative to the previous version of that claim. A parenthetical expression should follow the claim number indicating the status of the claim, e.g., "amended," "twice amended," etc. The parenthetical expression "amended," "twice amended," etc. should be the same for both the clean version of the claim under paragraph (c)(1)(I) of this section and the marked up version under this paragraph. The changes may be shown by brackets (for deleted matter) or underlining (for added matter), or by any equivalent marking system. A marked up version does not have to be supplied for an added claim or a canceled claim as it is sufficient to state that a particular claim has been added, or canceled.

(2) A claim canceled by amendment (deleted in its entirety) may be reinstated only by a subsequent amendment presenting the claim as a new claim with a new claim number.

(3) A clean version of the entire set of pending claims may be submitted in a single amendment paper. Such a submission shall be construed as directing the cancellation of all previous versions of any pending claims. A marked up version is required only for claims being changed by the current amendment (see paragraph (c)(1)(ii) of this section). Any claim not accompanied by a marked up version will constitute an assertion that it has not been changed relative to the immediate prior version.

3. It is unclear to the examiner if, for example, the phrases bracketed by either "[]" or "{ }" in steps 7.-9, 29., 32., 46., and 67. are to be deleted or not, because of the bracketing. **Please clarify.**

The examiner did see the comment on page 14 of the amendment wherein the applicant attempted to clarify what was intended by the bracketing. However, the printer will see the brackets and delete that language from the claim as matter of habit. Please try to avoid all bracketing. Dashes or parentheses would be acceptable.

SEQUENCE RULES

4. This application still fails to comply with the requirements of 37 CFR 1.821 through 1.825. The CRF was technically flawed and could not be entered into the database. See the Notice to Comply with the Requirements for Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

CLAIM OBJECTIONS

5. Claim(s) 1 is /are is objected to for the following two minor informalities.

a. Reason 1

Please note the following comments which are derived from the MPEP and relate to the preferred form of the claims. Note especially the print in bold type.

MPEP 608.01(m) [R-1] Form of Claims

The claim(s) must commence on a separate sheet and should appear after the detailed description of the invention. While there is no set statutory form for claims, the present Office practice is to insist that each claim must be the object of a sentence starting with "I (or we) claim", "The invention claimed is" (or the equivalent). If, at the time of allowance, the quoted terminology is not present, it is inserted by the clerk. Each claim begins with a capital letter and ends with a period. **Periods may not be used elsewhere in the claims except for abbreviations. See Fressola v. Manbeck, 36 USPQ2d 1211 (D.D.C. 1995). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation, 37 CFR 1.75(l).**

There may be plural indentations to further segregate subcombinations or related steps. In general, the printed patent copies will follow the format used but printing difficulties or expense may prevent the duplication of unduly complex claim formats. **Reference characters corresponding to elements recited in the detailed description and the drawings may be used in conjunction with the**

recitation of the same element or group of elements in the claims. The reference characters, however, should be enclosed within parentheses so as to avoid confusion with other numbers or characters which may appear in the claims.

♦ **Note that the use of numbers with periods within the claim is improper.**

The use of reference characters is to be considered as having no effect on the scope of the claims.

♦♦ **Note:** changing the numbers in the claim to ... numbers or letter in parentheses would be acceptable. For example "1." on line 3 can be changed to (1) or 1) or (a) or a)

b. Reason 2

The word "scraping" in step 3 is misspelled as "scrapping". In addition the word "storing" in step 27 is misspelled as "storeing".

35 USC § 112- 2ND PARAGRAPH

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

CLAIM REJECTIONS under 35 USC § 112- 2ND PARAGRAPH

7. **Claim(s) 1** is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected as prolix. According to the MPEP at 2173.05(m), Examiners should reject claims as prolix when they contain such long recitations or unimportant details that the scope of the claimed invention is rendered indefinite thereby. Claims are rejected as prolix when they contain long recitations that the metes and bounds of the claimed subject matter cannot be determined.

Also, **Claim 1** is indefinite because the phrase "frozen cell pellets from on ice" in step 29 lacks proper antecedent basis in Claim 1. It appears the applicant is referring to the frozen nuclear pellet stored at -86°C in step 24. Please clarify. Step 35 is non-sequitur probably because of the phrase "was removed". In addition, **Claim 1** is indefinite because it is unclear to which nuclear or cytoplasmic extracts the claim refers in step 63.

Finally, it is unclear to the examiner how step 68 results in the simultaneous isolation of biologically active transcription factors and DNA. The use of the phrase "whereby simultaneous isolation of biologically active transcription factors and DNA is accomplished" at this point in the claim is non-sequitur. Are not the last 20 steps or so related only to the analysis of the isolated DNA and biologically active transcription factors and not to the actual isolation thereof. It would appear these steps are unnecessary and do not contribute to the actual isolation of biologically active transcription factors and DNA.

35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

CLAIM REJECTIONS UNDER 35 USC § 103

9. Claim(s) 1 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Das et al. (1990).

Das et al. teach the simultaneous isolation of DNA, RNA, and protein (i.e. biologically active transcription factors) without the use of ultracentrifugation. Admittedly, Das et al. do not explicitly teach each and every limitation of the claimed method, however, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to determine the most appropriate buffer(s)/method steps to simultaneously isolate DNA and protein (i.e. biologically active transcription factors) from a biological source using easily accomplished modifications (i.e. optimizations) of the basic method outlined by Das et al. Where the general conditions of a claim are disclosed in the prior art, it is not inventive, in the absence of an unexpected result, to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

EXAMINER'S COMMENTS/ REQUESTS

10. The examiner has tried repeatedly to obtain a copy of Dr. Caruccio's dissertation but to date has been unable to obtain it. If you have a copy, its inclusion into the record via a PTO-1449 would be greatly

appreciated. Absent that, a paper wherein the applicant declares that the claimed method is not disclosed in Dr. Caruccio's dissertation would suffice.

Claim(s) 1, as drawn, is **very** narrow in scope and appears to be novel over the prior art as a result, however, it unclear to the examiner which of the limitation(s) make the claim novel over the prior art, as all of the steps seem very routine. See for example, Das et al. Methods in Molecular Biology Vol. 1, No. 5/6, pp. 213-222 (1990) who teach the simultaneous isolation of DNA, RNA, and protein (i.e. biologically active transcription factors) without the use of ultracentrifugation. Admittedly, Das et al. do not explicitly teach each and every limitation of the claimed method but absent some secondary consideration or an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to determine the most appropriate buffer(s)/method steps to simultaneous isolate DNA, RNA, and protein (i.e. biologically active transcription factors) from a biological source by optimizing the basic method outlined by Das et al.

CONCLUSION

11. **Claim(s) 1** is/are rejected and/or objected to for the reason(s) set forth above.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Art Unit is (703) 308-8724. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.


ETHAN C. WHISENANT
PRIMARY EXAMINER